

STATE OF CALIFORNIA
AIR RESOURCES BOARD

AIR MONITORING QUALITY ASSURANCE

VOLUME V

AUDIT PROCEDURES MANUAL

APPENDIX AG

SYSTEM AUDIT PROCEDURES FOR
PESTICIDE MONITORING PROGRAMS

MONITORING AND LABORATORY DIVISION

JULY 2001

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SYSTEM AUDIT PROCEDURES FOR PESTICIDE
MONITORING PROGRAMS

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SYSTEM AUDIT PROCEDURES
FOR PESTICIDE MONITORING PROGRAMS

MONITORING AND LABORATORY DIVISION

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AG.1.0 **SYSTEM AUDIT PROCEDURES FOR PESTICIDE MONITORING PROGRAMS**

AG.1.0.1 INTRODUCTION - A system audit of a pesticide monitoring program is an on-site review and inspection of laboratory operations and sample collection procedures to assess compliance with established guidelines governing the collection, analysis, validation, and reporting of pesticide data. A system audit is normally conducted at the initiation of a new monitoring program and includes an appraisal of the following program areas: network management, field and laboratory operations, data management and reporting, and quality assurance. On-site interviews should include a review of the data processing procedure from field acquisition through reporting of the data.

The system audit is facilitated by the use of a questionnaire designed to provide information about specific portions of the overall program. This questionnaire can be used to provide a system audit of the whole program, or sections of it individually, to provide an audit on a portion of the program.

This procedure addresses the sampling and laboratory evaluations of a system audit, including an evaluation of the sampling and laboratory standard operating procedures (SOP).

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GUIDELINES FOR CONDUCTING SYSTEM AUDITS

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AG.1.1 GUIDELINES FOR CONDUCTING SYSTEM AUDITS

A system audit should consist of three separate phases:

- Pre-audit Activities
- On-site Audit Activities
- Post-audit Activities

AG.1.1.1 PRE-AUDIT ACTIVITIES - Pesticide monitoring system audits are not conducted on a routine basis. Pesticide monitoring programs are often special projects. A tentative schedule for on-site system audits of the field sites and laboratories should be established as soon as the auditor can arrange it. As part of this scheduling, the auditor should indicate any special requirements, such as access to specific areas or observation of specific activities.

The auditor should arrange a tentative schedule for meetings with key personnel, as well as for inspection of the laboratory and field sampling sites. The auditor should also inform both the laboratory and field staff that they will each receive a questionnaire which is to be completed and returned to the auditor as soon as possible. Once the completed questionnaires have been returned, they will be reviewed, and the auditor will prepare a checklist detailing specific points for discussion. The auditor should contact the laboratory and field staff and coordinate the on-site audits.

AG.1.1.2 ON-SITE AUDIT ACTIVITIES - The auditor should meet initially with the program's contact person or his/her designee to discuss the scope, duration, and activities involved with the audit. This should be followed by a meeting with key personnel identified from the completed questionnaire. Key personnel to be interviewed during the audit are those individuals with the responsibilities for: oversight of field and laboratory operations, data management and reporting, and quality assurance/quality control (QA/QC). The checklist of detailed specific points may be discussed during these meetings.

Enough time and effort should be devoted to the system audit so the auditor has a clear understanding and complete documentation in the following areas:

1. Organization

- organization, training, and background of key personnel
- general information on status of laboratory program, QA plan, and field and laboratory's SOP

2. Field Operations

- although sampling operations are often conducted by another group not affiliated with the laboratory, details of field operations which affect data quality should be determined by laboratory personnel if the Sample

Handling/Field Operations section of the Pesticide System Audit Questionnaire is not completed by field staff.

3. Laboratory Operations

- operational practices for manual methods
- analytical methods used
- use of SOP, QC use of blanks, duplicates, and calibrations
- corrective actions, repeat sample analysis
- documentation and traceability for standards
- record keeping, chain-of-custody, logbooks
- waste disposal, safety practices, adequacy of laboratory for needs
- data acquisition, data flow, back-up, and validation

4. Data Management

- data flow from field and laboratory to data processing
- overview of data entry, automatic or manual
- control check methods: if automatic, software and system
- system backup and recovery capabilities
- data screening, flagging, validation, correction (who may correct?)
- type of reports and responsibility for final validation

5. QA/QC Programs

- status and implementation of procedures
- outside audits
- internal audits such as document reviews or data processing
- implementation of corrective action
- frequency, levels, and results of precision checks for each pesticide

6. Reporting

- precision and accuracy summaries
- internal reports to track performance and corrective actions
- summary of data reports as required, completeness and validity

In order to facilitate gaining a complete understanding of the pesticide monitoring program, the auditor should conduct a random spot check of the program's documentation and obtain sample copies of the following:

- logs (daily calibration checks, maintenance, etc.)
- calibration reports (field and laboratory)
- quarterly QC report
- monthly QC report
- organizational chart

Once the on-site system audit is complete, the auditor should meet again with key personnel to present preliminary findings and possible recommendations. The

auditor should state the audit results and include an indication of the potential data quality impact. This is also an opportunity for the laboratory to provide feedback.

The potential data quality impact is based upon specific criteria, some of which are requirements, and others which are only recommendations to improve the quality of a program.

AG.1.1.3 POST-AUDIT ACTIVITIES - The major post-audit activity is the preparation of the System Audit Report. The preparation of this audit report requires the auditor to compare the documented SOP with the observed accomplishments and deficiencies of the audit findings.

A preliminary draft System Audit Report is submitted to the program contact, together with a letter requesting comments and thanking both the laboratory and field personnel for their assistance, time, and cooperation.

If written comments or questions were submitted, concerning the audit report, they should be reviewed for incorporation into a final draft report within 30 days of receipt of the written comment. If no written comments are received within 30 calendar days from report date, the report will be formally distributed without further changes.

The System Audit Report should include the following:

- executive summary
- conclusion
- recommendations
- system audit objectives
- organization
- laboratory facility and operations
- field operations
- data management
- quality assurance and quality control
- data quality
- follow-up

The audit results should include information on the staff and equipment, network size, data management system, quality assurance, and quality control functions.

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CRITERIA FOR EVALUATION

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AG.1.2 CRITERIA FOR EVALUATION

AG.1.2.1 INTRODUCTION - A system audit is normally conducted in four steps. First, a questionnaire is sent prior to the audit visit. Staff should fill out the questionnaire as completely as possible and return it with sufficient documentation through the use of attachments. Second, the questionnaire is reviewed by the auditor to become familiar with the system operations and to determine any weaknesses and potential problem areas. Third, the on-site visit and interviews are scheduled. Fourth, a report with recommendations is prepared and discussed with the appropriate staff.

During the audit, the auditor should interview the appropriate managers, and any persons who have direct responsibility for field operations, pesticide analysis, data validation, data analysis, data reporting, and quality assurance. The information gathered from these interviews should be complete and up-to-date. The interviews should also present an adequate picture of the current and proposed levels of implementation of all quality assurance activities, including internal quality control. An evaluation of the data handling and processing, field and laboratory operations and procedures, QA/QC, and analytical process should be conducted at this time.

At the conclusion of the series of interviews and the evaluations, the auditor should inform the program contact person of the audit results and discuss any potential data-impacting problems uncovered. At this time, the auditor also explains the reporting procedures and schedule.

AG1.2.2 QUESTIONNAIRE - An overall system audit questionnaire is intended for use when a complete system audit is being conducted. This questionnaire covers field as well as laboratory operations. The overall system audit questionnaire should be completed by the person responsible for the overall program and should be returned to the auditor.

The questionnaire includes several areas: sample handling/field operations, laboratory equipment and instrumentation, instrument calibration, method validation, quality control samples, and documentation. This questionnaire is intended to cover all aspects of the pesticide monitoring program.

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PESTICIDE SYSTEM AUDIT QUESTIONNAIRE

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AG.2.0 PESTICIDE SYSTEM AUDIT QUESTIONNAIRE

Agency/Laboratory _____

Address _____

Telephone Number (____)_____ FAX (____)_____

Lab Director/Supervisor _____

Field Supervisor _____

Chemist(s) Responsible for Analysis _____

Target Pesticide(s) _____

Date Questionnaire Completed _____ By Whom _____

Quality Assurance Auditor(s) _____

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A. SAMPLE HANDLING/FIELD OPERATIONS

- | | | |
|----|---|--------------|
| 1. | a) Is there an SOP for sample collection/field operations? | YES[] NO[] |
| | b) Are sampling dates and times specified? | YES[] NO[] |
| | c) Are background sites specified? | YES[] NO[] |
| 2. | a) Are sampler flow rates calibrated prior to use in the field? | YES[] NO[] |
| | b) Are sampler flow rates checked in the field?
How often?_____ | YES[] NO[] |
| | c) Are sampler flow rates checked after use in the field? | YES[] NO[] |
| 3. | a) Is a sample field log or data sheet kept? | YES[] NO[] |
| | b) If YES, which of the following information is included on the field log or data sheet? | |
| | 1. Sampler Location - | YES[] NO[] |
| | 2. Sampling Date - | YES[] NO[] |
| | 3. Start and Stop Times- | YES[] NO[] |
| | 4. Initial and Final Flow Rates- | YES[] NO[] |
| | 5. Comments about Unusual Conditions - | YES[] NO[] |
| | c) Is a copy of the field log or copies of the field data sheets shipped with the samples? | YES[] NO[] |
| 4. | a) Are chain-of-custody forms utilized? | YES[] NO[] |
| . | b) Are they shipped with the samples? | YES[] NO[] |
| 5. | After sampling, how long are samples stored in the field before being shipped to the laboratory for analysis? _____ | |
| 6. | a) Are samples cooled during shipping and storage? | YES[] NO[] |

A. SAMPLE HANDLING/FIELD OPERATIONS (cont.)

- b) If YES, how are the samples cooled and what temperature is maintained, before shipping from the field? _____

- c) How are they cooled during shipping and what temperature is maintained, during shipping ? _____

- d) If ice was used, was it still present when the samples were received at the lab? YES[] NO[]
- e) Was the temperature of the samples when received at the lab? YES[] NO[]
If YES, what was it? _____
7. a) Are samples enclosed in a protective container during shipping and storage? YES[] NO[]
b) What type? _____

8. What mode of transportation is used to ship samples? _____

9. What vendor supplied the sampling medium? _____

10. How long are samples stored in the laboratory before:
a) Extraction? _____
b) Analysis? _____
11. How long are samples stored after analysis? _____

12. a) Have stability studies been conducted to verify the integrity of the samples? YES[] NO[]
b) Summarize the results of the studies: _____

B. LABORATORY EQUIPMENT AND INSTRUMENTATION

1. List the laboratory instrumentation used in the analysis of the target pesticide(s)
 - a) Chromatograph: _____

 - b) Detector: _____

 - c) Other Analytical Instrumentation: _____

2. Is there a computer interface for data handling? YES[] NO[]
3. a) Are refrigerator(s) or freezer(s) used? YES[] NO[]
 - b) If Yes, what is/are the temperature setting(s)? _____

C. INSTRUMENT CALIBRATION

1. What is the frequency of instrument calibration? _____

2. Briefly, describe the calibration procedure. _____

3. Are the calibration results documented? YES[] NO[]

If YES, where are they documented? _____

C. INSTRUMENT CALIBRATION (cont.)

4. What type of standards are used for calibration? _____

5. Where are the materials for the standards obtained? _____

6. Briefly, describe the preparation of the standards. _____

- a) What is the frequency of standard preparation? _____

- b) What is the stability of the standards? _____

7. What are the concentrations of the calibration standards? _____

8. a) Are the standards labeled? YES[] NO[]
- b) If YES, which of the following information is contained on the labels?
- Check all that apply.
- | | |
|----------------------|--------------|
| 1) Date Prepared | YES[] NO[] |
| 2) Solvent | YES[] NO[] |
| 3) Chemist | YES[] NO[] |
| 4) Expiration Date | YES[] NO[] |
| 5) Other (describe): | |
9. Where/how are the standard solutions stored? _____

D. METHOD VALIDATION

1. a) Is the analytical procedure documented in an SOP and available for review? YES[] NO[]
b) Title of SOP/description of analytical procedure. _____

2. Indicate the source of the analytical procedure:
a) U.S. EPA YES[] NO[]
b) NIOSH YES[] NO[]
c) ASTM YES[] NO[]
d) Laboratory development YES[] NO[]
e) Other
3. Has the method been validated for the following:
a) Limit of Detection (LOD) YES[] NO[]
By what criteria? _____

What is the LOD? _____

b) Limit of Quantitation (LOQ) YES[] NO[]
By what criteria? _____

What is the LOQ? _____

D. METHOD VALIDATION (cont.)

c) Trapping Efficiency? YES[] NO[]

Percent Efficiency?_____

d) Method Recovery? YES[] NO[]

Percent recovery?_____

e) Breakthrough? YES[] NO[]

Mass Load_____

Flow Rate_____

Time_____

f) Precision of Injection Results? YES[] NO[]

What are the precision limits?_____

How are the precision limits determined?_____

E. QUALITY CONTROL SAMPLES

1. Are control samples analyzed? YES[] NO[]

Frequency of control samples_____

2. a) Are control/warning limits defined? YES[] NO[]

b) Describe the guidelines._____

c) What procedures are followed when the control limits are not attained?_____

E. QUALITY CONTROL SAMPLES (cont.)

- d) Are control sample results graphed on a control chart? YES[] NO[]
3. Are laboratory spikes analyzed routinely? YES[] NO[]
- Frequency_____
- Percent Recovery _____
4. a) Are field spikes included routinely? YES[] NO[]
- Frequency_____
- Percent Recovery_____
- b) If YES, do field spikes include blind spike samples? YES[] NO[]
5. Are laboratory blanks analyzed on a routine basis? YES[] NO[]
- Frequency_____
- Type (e.g., solvent, instrument, system)_____
6. Are field or trip blanks included with each shipment of samples? YES[] NO[]
7. Are samples analyzed in replicate to document analytical precision? YES[] NO[]
- Frequency_____
8. Are field samples from collocated sites included in the monitoring and analysis? YES[] NO[]
- Frequency/Number_____
9. Are a portion of the samples analyzed by another method to confirm the identity of the analyte? YES[] NO[]
- If YES, by what method?_____
- _____
10. Are all quality control records available for review? YES[] NO[]

F. DOCUMENTATION

- Are all samples received by the laboratory logged-in? YES[] NO[]
1. Are all samples received in the laboratory assigned a unique laboratory sample number? YES[] NO[]
2. Does the laboratory have an established chain-of-custody documentation system? YES[] NO[]
3. Does each instrument have a maintenance and repair log? YES[] NO[]
4. Are bound books used in the laboratory?
Are the pages numbered? YES[] NO[]
5. Do laboratory records include:
- a) Sample Identification Number YES[] NO[]
- b) Sample Type YES[] NO[]
- c) Date Sample Received in the Lab YES[] NO[]
- d) Collection Data (flow rate, time, date, etc.) YES[] NO[]
- e) Date of Analysis YES[] NO[]
- f) Results of Analysis YES[] NO[]
- g) Name of Analyst YES[] NO[]
7. Are final reports completely traceable to the original raw data? YES[] NO[]
8. Are final reports reviewed against chain-of-custody records to ensure that the files are complete? YES[] NO[]
9. Are data and calculations reviewed and verified against laboratory records before reports are released? YES[] NO[]

By Whom? _____

F. DOCUMENTATION (cont.)

10. Are records kept in an orderly, accessible form? (This includes all raw data, calculations, quality control data, and reports.) YES[] NO[]

How long are records kept?_____

11. Are the original raw data available for review? YES[] NO[]

12. Are the data electronically stored? YES[] NO[]

If YES, how are the records backed up?_____

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SAMPLING OPERATIONS EVALUATION

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AG.3.0 SAMPLING OPERATIONS EVALUATION

- AG.3.0.1 PROCEDURE- A field sampling operations system audit follows the procedures outlined in Section AG.1.2, Criteria for Evaluation. The system audit consists of four steps: 1) completion of portions of the Sample Handling/Field Operations section of the Pesticide Air Monitoring Laboratory Questionnaire, 2) reviewing the completed questionnaire, 3) conducting the on-site visit and interviews, and 4) issuing a report with comments and recommendations.

During the on-site visit, the auditor should interview the technician responsible for collecting the samples and recording data. The information gathered from these interviews should present an accurate picture of the current and proposed implementation of all quality assurance activities. An evaluation of the field operations, procedures, and QA/QC should be conducted at this time. This evaluation should consist of, at a minimum, a random verification of sampling records.

At the conclusion of the interviews and evaluations, the auditor should inform the technician and laboratory contact person of the audit results and discuss any potential data-impacting problems uncovered. At this time, the auditor also explains the reporting procedures and schedule.

- AG.3.0.2 GENERAL GUIDANCE FOR SAMPLING DOCUMENTATION - All QA/QC documents such as Chain of Custody, logbooks, sampling SOPs, etc., should be available for review. Any problems determined from these documents and the potential affect on data quality should be noted. The field technician and laboratory management should be notified of any problems.

- AG.3.0.3 SITE EVALUATION REPORTING - At the conclusion of a sampling evaluation, the auditor should prepare a brief written report (refer to Section AG.1.1.3). This report should contain at least a discussion of observations made during the site visit as noted in the questionnaire, and a copy of the documentation used for the evaluation. Where major discrepancies are noted, additional information needs to be included. Recommendations to improve sampling procedures should be included.

- AG.3.0.4 QUESTIONNAIRE - The Sample Handling/Field Operations section of the questionnaire should be completed by the person involved in sample collection and handling, operations of the sampling site, and field activities quality control. The completed section of the questionnaire will provide information on sampling documentation and field evaluation (see Pesticide System Audit Questionnaire, Section A).

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LABORATORY OPERATIONS EVALUATION

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AG.4.0 LABORATORY OPERATIONS EVALUATION

- AG.4.0.1 PROCEDURE - A laboratory system audit follows the procedures outlined in Section AG.1.2, Criteria for Evaluation. The system audit consists of four steps: 1) completion of the Pesticide System Audit Questionnaire, 2) reviewing the completed questionnaire, 3) conducting the on-site visit and interviews, and 4) issuing a report with comments and recommendations.

During the on-site visit, the auditor should interview the laboratory manager and any person who has direct responsibility for: pesticide analysis, data validation, data reporting or quality assurance. The information gathered from these interviews should present an accurate picture of the current and proposed implementation of all quality assurance activities, including internal quality control. An evaluation of the data handling, processing, laboratory operations, laboratory procedures, QA/QC, and analytical process should be conducted at this time.

At the conclusion of the series of interviews and evaluations, the auditor should inform the laboratory manager of the audit results and discuss any potential data impacting problems uncovered. At this time, the auditor also explains the reporting procedures and schedule.

- AG.4.0.2 GENERAL GUIDANCE FOR LABORATORY DOCUMENTATION - All QA/QC documents such as Chain of Custody, logbooks, sampling SOPs, etc., should be available for review. Any problems determined from these documents and the potential affect on data quality should be noted. The laboratory management should be notified of any problems.

- AG.4.0.3 LABORATORY EVALUATION REPORTING - At the conclusion of a laboratory evaluation, the auditor should prepare a brief written report (refer to Section AG.1.1.3). This report should contain at least a discussion of observations made during the site visit as noted in the questionnaire, and a copy of the documentation used for the evaluation. Where major discrepancies are noted, additional information needs to be included. Recommendations to improve sampling procedures should be included.

- AG.4.0.4 QUESTIONNAIRE - A laboratory questionnaire (if not part of the system audit questionnaire) provides information on analytical methods, standard laboratory operations, data entry, data bank validation, laboratory quality control, and laboratory management. The laboratory system audit questionnaire should be completed by every person involved in the data entry and review process, and by every person responsible for the operation of an analytical instrument (see Pesticide System Audit Questionnaire, Sections B through F).

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REFERENCES

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1. ARB "Quality Assurance Plan for Pesticide Monitoring".
1. 40 CFR 50, July 1996.
2. 40 CFR 53, July 1996.
3. 40 CFR 58, July 1996.
4. U.S. EPA "Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II."
5. ARB "Air Monitoring Quality Assurance, Volume V".